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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,885

03/01/2004

Richard Kaplan

086524-0010

2598

8568

7590

02/18/2009

DRINKER BIDDLE & REATH LLP
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CHICAGO, IL 60606

EXAMINER

GILBERT, SAMUEL G

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,885

Applicant(s)

KAPLAN ET AL.

Examiner

Samuel G. Gilbert

Art Unit

3735

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38 and 40-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71-76 is/are allowed.
- 6) ☒ Claim(s) 38, 40-43, 46, 47, 50-54, 61 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 44, 45, 48, 49, 55-60, 62-66 and 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 - is written as dependent on canceled claim 39 making the scope of the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 40, 41, 46, 47, 50-54, 61 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Katims (4,503,863).

Claim 38 - element -17- is a determination means for producing information indicative of the subjects wake sleep state, applicants attention is invited to column 5 line 65 through column 6 line 40 and element -12- is a means for implementing stimulus control therapy, column 5 lines 37-45.

Claim 40 - (for purposes of the merits the examiner is considering claim 40 to depend from claim 38 not 39) stimulator -12- includes controls to choose the therapy to be implemented, column 8 lines 57-63.

Claim 41 - the determination means uses sets forth many of the claimed means in column 6 lines 1-7 and 41.

Claim 46 - the device is optimized for each subject as set forth in column 2 lines 4-7

Claim 47 - element -17- is a determination means for producing information indicative of the subjects wake sleep state, applicants attention is invited to column 5 line 65 through column 6 line 40 and element -12- is a means for implementing stimulus control therapy, column 5 lines 37-45.

Claim 50 - the device uses stimulus therapy.

Claim 51 - the individual may adjust the stimulator, column 10 lines 20-34. The examiner is considering these adjustments as set up adjustments.

Claim 52 - the profile described in column 2 lines 3-7 inherently includes wake/sleep state history when the device is used for treating insomnia.

Claim 53 - indicator lights 37 and 38 permit the subject to review information previously required.

Claim 54 - the computer computes statistics based on wake/sleep history (monitored EEG signal), column 7 lines 3-17.

Claim 61 - indicator lights 37 and 38 provide visual information.

Claim 69 - indicator lights 37 and 38 are visual prompts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katims (4,503,863) in view of Wyatt (6,392,962).

The apparatus of Wyatt teaches a device as claimed but does not include additional drug therapy or active sensing means. Wyatt teaches that it is old and well known to use drug therapy and active sensing means for the treatment of insomnia. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to include the active device and the drug therapy set forth in Wyatt. Such combination therapy would produce predictable results of a device using passive

and active sensing means and drug therapy to aid in the treatment of insomnia as is known in the art as set forth by Wyatt. The combination would have a high expectancy of success because the individual therapies are known in the art and selection of using them together is within the skill of one in the art.

Allowable Subject Matter

Claims 44, 45, 48, 49, 55-60, 62-68 and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 67 and 68 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 71-76 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/
Primary Examiner, Art Unit 3735